Improving patient reported outcome measures (PROMs) in total knee replacement by changing implant and preserving the infrapatella fatpad: a quality improvement project

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Abstract

Patient reported outcome measures (PROMs) were introduced in 2009 to allow patient perspectives to potentially influence change and improvement. In collaboration with the national joint registry (NJR), PROMs data has been examined on a national basis to compare surgical factors in total knee replacement (TKR). Initial results demonstrated there were statistically significant differences in Oxford Knee Score (OKS) when using different brands of implant. Preservation of the infrapatella fatpad (IFP) has also been shown improve outcomes. This led Northumbria Healthcare NHS Foundation Trust to make a mass move to the Zimmer Nexgen TKR and later change surgeons' routine practice to preserving the IFP. The PROMs were recorded pre and six months post operation to obtain improvement scores. The baseline improvement in OKS was 14.0. After changing implant to the Zimmer Nexgen in Plan-Do-Study-Act (PDSA) cycle 1 the average improvement score was 16.7. After implementing default preservation of the IFP in PDSA cycle 2 the average OKS improvement score was 17.3. The results from this project demonstrate a significant improvement in local services after implementing changes based on national and local evaluations. This initiative is an excellent example of improvement by evidence based practice and success of the English National Health Service PROMs scheme.

Problem

Northumbria Healthcare NHS Foundation Trust (NHCFT) provides healthcare to over half a million people from North Tyneside to the Scottish borders. 14 Orthopaedic Surgeons in NHCFT perform over 1200 total knee replacements (TKR) every year with demand likely to increase. In line with national standards, Patient Recorded Outcome Measures (PROMs) in total knee replacement (TKR) have been routinely collected to compare outcomes against other units. Published PROMs from the Health & Social Care Information Centre (HSCIC) in August 2011 showed that NHCFT had an average health gain improvement score of 14.65 compared to the national average of 14.75 after case-mix adjustment. The aim of this project was to improve NHCFT's PROMs post TKR after implementation of evidence-based change in practice.

Background

The purpose of any medical intervention is to improve patients' health. This improvement has traditionally been measured by the clinician irrespective of patient judgment.[1] Patient reported outcome measures (PROMs) were introduced in 2009 by the National Health Service (NHS) in England initially focusing on hip and knee replacement, hernia, and varicose vein surgery. This was the first of its kind internationally allowing patient perspectives to potentially influence change and improvement. The data collected has been used to compare and analyse quality of services and providers, with the intention to reward high performing trusts financially for good results. Whilst it is difficult to influence patient factors, surgical technique and implant choice have been scrutinized for their effect on patient outcome.[2]

Total knee replacement (TKR) is an established and successful surgical intervention for knee arthritis with the intended benefit being pain relief and functional improvement.[3] Arguably it is the patient who is best placed to measure outcome and indeed success. The oxford knee score (OKS) and healthcare status score EQ-5D-3L were selected as PROMs for patients undergoing knee replacement. The EQ-5D index is a well-established measure of health status and outcomes. OKS was first described in 1998 as a way of removing surgeon bias and could be completed remotely by the patient. It involves a 12-item questionnaire regarding pain and function to produce a score out of 48. The scoring system and questions have evolved and been modified over time but are now universally recognised as the gold standard outcome measure for knee replacement.[4]

By analysing PROMs clinicians and managers can adjust their practice to seek the best outcome and improve patient satisfaction. In collaboration with the National Joint Registry of England and Wales (NJR), PROMs data has been examined on a national basis to compare surgical factors. Baker et al (2012) studied the results from over 20,000 patients who underwent TKR from 2008 to 2011.[2] One of the paper's most notable findings was the variation on improvement in PROMs when comparing different implant brands. Previous studies had reported no significant difference in knee replacement brand or type but were not conducted on such scale.[5,6]

Excision of the infrapatella fatpad (IFP) remains controversial amongst orthopaedic surgeons in TKR. Some would argue the fatpad has an important role in the blood supply to the patella tendon, biomechanics of the knee, and as an inflammatory modulator. Others would advocate its excision for improved access

and visualisation.[7-9] Moverley et al (2014) demonstrated improved PROMs outcome scores in a study of over 1400 patients when the IFP was preserved.[10]

Baseline measurement

Pre operative PROMs in the form of OKS and EQ-5D are collected by the trust. The HSCIC send out six month post operative questionnaires and are responsible for linking the scores together. From April 2009 to March 2011 827 TKRs were identified with completed OKS and EQ-5D scores out of a possible 1902 TKRs performed (43.5%). The overall average OKS improvement score was 14.0 (95% CIs 13.3-14.6) and average EQ-5D index improvement score was 0.258 (95% CI 0.237-0.280).

Design

The two implants at the time were the Anatomic Graduated Component (AGC) by Biomet, Swindon, UK and the PFC by Depuy, Warsaw, Indiana, US. The PROMs analysis by Baker et al (2012) demonstrated that average OKS improvement in the AGC and PFC was 14.9 and 15.2 respectively. The Nexgen TKR (Zimmer, Swindon UK) implant was significantly better than all other knee replacements with an average OKS improvement of 16.2.[2] Furthermore studies from the Australian and Swedish joint registries demonstrated that the Nexgen TKR had the lowest revision rate.[11,12] This prompted all NHCFT knee replacement surgeons to make a mass move to the Nexgen TKR based on the PROMs and registry results. This was specifically to improve the outcome for patients but there was a perception that provider outcomes would be subject to remuneration within the coming years. Best Practice Tariff of around £500 per case for TKR has now been introduced with requirements including PROMs participation and average health gain.

Strategy

PDSA cycle 1. A business plan was drawn up and presented to the department proposing a six month changeover period to the Zimmer Nexgen for all patients undergoing TKR. This would allow the significant step of retraining theatre staff, surgeons, and sterile services. After board approval the Nexgen TKR was introduced in September 2011 with the transition period extending to March 2012. To compare improvement scores before and after the change to the Nexgen TKR routine pre operative and six month post operative PROMs in the form of OKS and EQ-5D were obtained from the HSCIC. These were anonymised datasets as no patient identifiable information was required. Due to the transition period to establish the Nexgen in late 2011 the data collected from the year April 2011 to March 2012 was not analysed. Improvement scores were then compared by analysis of variance (ANOVA) to test for significance. There were 1,617 Nexgen TKRs with completed records from April 2012 to October 2014 out of a possible 3006 TKRs performed (53.8%). There was no significant difference in pre operative scores. The average OKS improvement score post implementation of the Nexgen TKR was 16.7. The average EQ-5D index improvement score was 0.311.

PDSA cycle 2. Following the improvement by changing implant the results from Moverley et al (2014) led NHFCT to analyse it's own practice on excision or preservation of the IFP. Out of 14 knee arthroplasty surgeons, the four consultants whose default practice was to preserve the IFP had significantly better TKR PROMs than those who excised it. These local results were fed back to each surgeon encouraging the IFP excisers to modify their surgical technique in favour of preserving the IFP with the aim to improve PROMs further. After this local study in November 2014, 441 TKR PROMs have been collected up to December 2015 with completed OKS and EQ-5D scores out of a possible 782 TKRs performed (56.4%). The average OKS has improved to 17.3 and the average EQ-5D index score has improved to 0.349.

Results

After implementation of the Nexgen TKR in PDSA cycle 1 the average OKS improvement score was 16.7 (95% CIs 16.2-17.1); significantly higher than the previously used TKRs grouped average 14.0 (p<0.001). The average EQ-5D index improvement score in the Nexgen TKRs of 0.311 (95% CIs 0.295-0.327) was significantly higher than the pre change average score of 0.258 (p<0.001). After default preservation of the IFP in PDSA cycle 2 the average OKS has improved to 17.3 (95% CIs 16.4-18.2) but has not reached statistical significance (p=0.208) when comparing to the PDSA 1 group. The average EQ-5D index score had significantly improved further to 0.349 (95% CIs 0.318-0.380), p=0.032.

Figures 1 and 2 show the improvement in OKS and EQ-5D average scores after PDSA cycles 1 and 2.

See supplementary file: ds7167.png - "Figures 1 and 2 showing the improvement in OKS and EQ-5D average scores after PDSA cycles 1 and 2."

Lessons and limitations

The 2014-15 HSCIC PROMs report demonstrated NHCFT had an average improvement in OKS of 17.1 after adjustment for case-mix compared to the national average of 16.1. The results from this project demonstrate a significant and sustained improvement in local services after implementing changes based on national and local evaluations. This initiative is a scalable example of improvement by evidence based practice and success of the NHS PROMs scheme.

It has been argued that to identify a clinically detectable change in OKS the difference has to be at least 4.[13] Our study reports a difference in improvement scores of 2.7 when comparing implants and 0.6 changing IFP practice. We acknowledge this is below a clinically detectable level for a particular individual but stress changing implant and preserving the IFP has transformed NHCFT's PROMs from below average to a high outlier when measured against the national average, and effects 1200 patients per year.

We have been unable to adjust for case-mix due to limitations in accessing patient identifiable information but have been able to

demonstrate that there was no significant difference in pre operative OKS between the groups. As all joint replacement patients were eligible to participate in the programme they were an unselected cohort and thus there is minimal risk of bias. The HSCIC are able to use statistical models to adjust for patient variables in order to allow fair comparison. After their method of adjustment NHFCT was deemed a high outlier for OKS and EQ-5D, after the changes.

Conclusion

The results show a greater OKS and EQ-5D index improvement after the trust moved to the Nexgen implant for primary knee replacements. The results are consistent with the improved scores demonstrated by a national analysis of over 20,000 TKRs. Preservation of the IFP has been shown to improve TKR outcome and after implementation of this guidance NHFCT's outcome scores have continued to improve. This is an excellent example of quality improvement by evidence-based practice, showcasing the national joint registry and PROMs agenda.

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Declaration of interests

Acknowledgements

Ethical approval

This analysis was performed on previously collected data. Patient identifiable data was not requested. As no new contact with patients was required this analysis was performed as a service evaluation designed primarily to improve patient outcome in TKR. As such formal ethic committee approval was not required.